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14. ABSTRACT
A Personal Health Monitor (PHM) for Ambulatory PTSD (and TBI) Assessment has been developed which integrates the collection of subjective health information, daily activities and behaviors, and objective physiological and environmental measurements in a handheld data collection system. Psychometric health scales can be used in concert with self-reported daily stressors and behavioral diaries, such as work stress, dietary intake, substance use, and exercise patterns. Passive monitoring of heart rate variability enables arousal assessment, while passive motion and location sensors enable indirect assessment of mobility, vigor, and social interaction. Clinicians and research investigators are able to customize data collection protocols by selecting a subset of available assessment, diary, survey and sensor modalities to suit their needs using a set of protocol definition files and database structures. Using mobile handheld computer and smart phone technology, the PHM enables psychological health assessments on a more continuous basis than traditional clinical encounters. The PHM enables collection of personal health data with privacy and anonymity, which may improve the quality, frequency, and accuracy of the psychometric assessments.

15. SUBJECT TERMS
PTSD, TBI, psychometric measures, personal health record, mobile, smart phone, handheld computer, Windows Mobile, physiological monitoring, observations in daily living

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1. INTRODUCTION

The goal of this project is to produce an easy-to-use Person Health Monitor (PHM) for longitudinal data collection and study of signs, symptoms, triggers, and behaviors in post traumatic stress disorder (PTSD) and mild traumatic brain injury (mTBI) patients. Currently there is little data for studying the dynamics of PTSD development and recovery, the relationship of symptoms to daily stressors and activities, behaviors that may affect or reflect mental status, or cognitive dysfunction, such as ability to maintain productive work. To enable such research, we are developing personal mobile technologies to acquire frequent, data collection during daily life. The challenge is to collect comprehensive, accurate, and integrated survey, physical, and physiological data while minimizing subject burden. Integration of data streams through a handheld platform is integral to our strategy for collecting complete and accurate information with low enough burden that patients will use the system daily over their course of therapy.

2. BODY

Research accomplishments attained during the first year are presented below, according to each task in the approved Statement of Work.

2.1. Task 1: Establish design requirements, development plans, and evaluation methods

To ensure quality in the work products, we employed a system development life cycle (SDLC) process for project management and system development, including software and hardware subsystems. The key benefits of this methodology are (1) defining requirements from user needs and (2) tracking requirements fulfillment throughout development, verification, and validation. The SDLC process encompasses all aspects of project management and system development, providing a framework to help ensure overall quality and that the developed products fulfill project goals and aims.

At the beginning of the project, a Project Plan was written to summarize all aspects of project management, including goals and objectives, proposed approach, listing of stakeholders and collaborators, identification of staff and resources, identification of key internal and external contacts, communications plans, identification of potential program and technical risks, and specification of technical processes to support quality research and development. The Project Plan was periodically reviewed and updated to reflect any changes in approach or processes that arose during the course of the work. The Project Plan laid out the overall framework for establishing design requirements, creating development plans, and defining evaluation methods.

2.1.1. Design Requirements

To establish design requirements, RTI investigators took the following steps:

a) Usability and burden data from a recent evaluation of a handheld system developed by RTI for Environmental Protection Agency (EPA) were examined to determine the feasibility adapting existing software and hardware components for the PHM. In the EPA project, over 50 participants used various system configurations to collect behavioral data on activities, location, food and beverage consumption, environmental conditions, and product use (Kizakevich et al, 2006, 2007; Whitmore, 2006). Each participants used the PFILES system for 7 days. We found the following results:

- 93% found the system easy to use, or had no opinion
- 87% found the system easy to carry, or had no opinion
- 67% found entering activity and location easy or very easy
- 92% found the daily diary review feature easy to add items
- 75% reported that they may or would likely repeat the study

These overwhelmingly positive results encouraged us to reuse the design concepts of this technology, and adapt and extend this technology for health and behavior assessment for longitudinal PTSD and TBI monitoring. User comments from the study debriefings would be examined to suggest revisions to the user interface and further improve device usability.

b) Since we are developing a both a research instrument for longitudinal studies of PTSD and TBI evaluation and a clinical tool for monitoring efficacy of various treatment regimens, we wanted to ensure that the design vision and system requirements would reflect the needs of relevant research and clinical applications. To do this, we employed a Use Case methodology. Use cases of clinical and experimental applications for the PHM were developed by our senior research psychologist, and reviewed with comment by Advisory Board members. Each use case comprised a brief one or two-page concept for an anticipated research or clinical use of the PHM in a PTSD or TBI study consistent with the Research Gaps identified in CDMRP PTSD/TBI program. The following use cases were developed:

- **UC1 – Combat Operational Stress Assessment**
  Objective: Assess the daily functioning of deployed service members to understand how stress develops over the course of deployment.

- **UC2 – Suicide Risk**
  Objective: Assess the potential for suicidal behavior (ideation, intent, attempt, completion) in order to implement improved methods of prevention, risk assessment, and emergency interventions.

- **UC3 – Therapeutic Intervention**
  Objective: Monitor service members to assess progress over the course of treatment, and support disposition recommendations such as readiness to return to duty, remain in limited duty capacity, or recommend separation.

- **UC4 – Health Behaviors**
  Objective: Assess post-deployment health behaviors of combat veterans to better understand the association between combat deployment and reintegration. Health behaviors can also be examined as a predictor for recovery from combat stress symptoms, development of PTSD and recovery from mTBI.

- **UC5 – Screening for and Tracking mTBI**
  Objective: Employ the Personal Health Monitor (PHM) to assist in mTBI screening, time-course, and commencement of rehabilitation for more rapid recovery.

- **UC6 – Family Stress**
  Objective: Understand the stress experienced by family members and the relationship to service member stress.

Each use case included the objectives, a clinical problem to be solved, research gap addressed, the research area addressed, the patient population of interest, hypotheses to be tested, methods, dependent measures, analyses and results, and conclusions and implications. It also included a set of psychological, physiological, social, and environmental measurements to be collected using the Personal Health Monitor, and the sampling interval (momentary, daily or weekly) for each measurement. The use cases are provided in Appendix A.

c) Based on the use case suggestions, we documented the psychometric instruments and other design requirements to be included in the developed system. At a minimum, the following measures were identified:

- **Baseline Instruments**
  - ? Demographics / Personal information
  - ? Health history
  - ? Combat exposure scale (CES)
  - ? Blast exposure scale (BES)
  - ? Concussion checklist
  - ? Post concussive syndrome (PCS)
  - ? 3 question DVBIC TBI screen (3QTBI)
  - ? Interpersonal social support list (ISEL-12)

- **Psychological Instruments**
  - ? PTSD checklist – Military (PCL-M)
  - ? Profile of mood states (mini-POMS)
  - ? Impact of event scale - revised (IES-R)
  - ? Beck anxiety inventory (BAI)
  - ? Perceived stress scale (PSS)
  - ? Pittsburgh sleep quality index (PSQI)
  - ? Hospital anxiety and depression scale (HADS)
  - ? Sheehan Disability Scale (SDS)

- **Behavioral Instruments**
    - ? Activity diary
    - ? Dietary diary
    - ? Beverage diary
    - ? Alcohol use disorders identification test (AUDIT)
    - ? Smoking
    - ? Duke activity status index (DASI)

- **Cognitive Instruments**
    - ? Simple Reaction Time
    - ? Procedural Reaction Time
    - ? Go-NoGo Reaction Time
    - ? Mathematical Reaction Time
    - ? Matching to Sample
    - ? Synthetic Work (SynWork)

- **Psychophysiological and Environmental Instruments**
    - ? Cardiac pulse for measuring heart rate, heart rate variability, and stress reactivity
    - ? Skin conductance for measuring psychophysical arousal
    - ? Cardiac bioimpedance for measuring cardiac stress reactivity
    - ? Respiratory sensors for measuring respiratory rate
    - ? GPS for assessing mobility and social interaction
    - ? Accelerometers for assessing mobility. sleep quality, and activity

d) We also identified the following features and specifications:

- Since psychometric scales are typically designed for monthly or weekly clinical assessments, we decided to develop a set of alternative scales for ambulatory self-entry on a momentary, daily, or weekly basis, as well as the original scales. For example, a leading phrase such as "In the last 30 days," could be replaced by "In the last week", "Last night", or "Currently." These alternative modes would allow for more frequent assessment, and would be selected by an investigator/clinician for a particular study or clinical evaluation.

- The PHM handheld data collection platform specifications are:
    - ? Windows Mobile 5.0 and 6.1 (now called Windows Phone) operating systems
    - ? Demonstrate functionality on a Smartphone
    - ? Demonstrate functionality on a handheld computer (i.e., PDA)
    - ? Attempt backward compatibility to Windows Mobile 2003

- Physiological sensors would be compatible with RTI's BodyPack technology

- Data storage will be encrypted using Microsoft SQL Server Compact Edition (CE)

- A Windows-PC based "dashboard" interface will be developed to facilitate the configuration of system settings according to the needs of expected research and clinical protocols. This dashboard interface will also facilitate the downloading of individual datasets, integration of individual data into a central database, data review for quality assurance (QA), report generations, and data exporting to other formats.

2.1.2. Development Plans and Actions

To develop the Personal Health Monitor components, RTI investigators took the following steps:

a) Design requirements were entered in a Requirements Traceability Matrix tracking sheet

b) Reference materials on PTSD, TBI, and psychometric testing were acquired

c) Resources for software development and testing were acquired, including:

- Microsoft Visual Studio 2008™, for VB.NET and C#.NET source code development

- Microsoft SQL Server CE for Windows Mobile database development

- Primeworks™ Data Port Wizard 2.1, for bi-direction conversion of Microsoft Access and Microsoft SQL Server CE databases

- Primeworks™ Data Console 1.5, for Microsoft SQL Server CE editing

- SOTI Pocket Controller – Professional™, for Windows Mobile software testing

d) Development partners were identified and collaborative arrangements made, including

- MLM Technical Services - subcontract for BodyPack instrumentation development

- Activity Research Services - subcontract for cognitive assessment development

e) Windows Mobile devices were acquired as development and testing resources, including

- The HTC Diamond Touch 2 Smartphone (Windows Mobile 6.1)

- The Hewlett-Packard iPAQ 210 handheld computer (Windows Mobile 5.0)

- The Hewlett-Packard iPAQ 4700 handheld computer (Windows Mobile 2003)

f) A project share drive was setup and configured for nightly backups.

2.1.3. Evaluation Methods

To develop the PHM evaluation methods, RTI investigators took the following steps:

a) Outlined a plan for functional testing of system components against the Requirements Traceability Matrix. Software modules will be tested by the developers as they are produced, and will include both individual module testing and incremental integrated testing. Full functionality testing will be led by a third party (non developer).

b) Reviewed evaluation procedures and usability questionnaires from previous similar projects, and developed a new usability questionnaire meeting this projects objectives

c) Evaluation partners were identified and collaborative arrangements made including

- TRJ Environmental - subcontract for system evaluation quality assurance

- Advisor Board members - hands-on review of prototype systems.

d) Discussed proposed evaluation plans with the Institutional Review Board Chairperson and determined that the evaluation methodology is Exempt according to federal regulations.

e) As the field evaluation plan is formalized, the IRB chairperson will be consulted to ensure that the protocol still meets criteria for Exempt status.

2.2.   Task 2: Develop handheld data collection system for ambulatory PTSD and TBI assessment

2.2.1.   Overall System Architecture

The overall architecture for the Personal Health Monitor system is shown below. Data collection is managed using a handheld computer (e.g., HP iPAQ) or a Windows Mobile smart phone (e.g., HTC Diamond Touch 2). Baseline information and subjective data are entered using self report forms and questionnaires. For collection of objective physical and physiological data, such as heart rate variability and cardiac reactivity, a small "BodyPack" device act as a wireless relay for chest belt sensors of heart pulse and, once developed, for respiratory monitoring and impedance cardiography. These will be used for measuring heart rate variability, cardiac stress reactivity, and respiratory rate. The BodyPack also provides sensors for body motion (3-axis accelerometer) and macro location (GPS receiver). The BodyPack acquires and preprocessed various sensor channels (i.e., pulse, GPS), and sends formatted data packets to the handheld device via Bluetooth wireless.
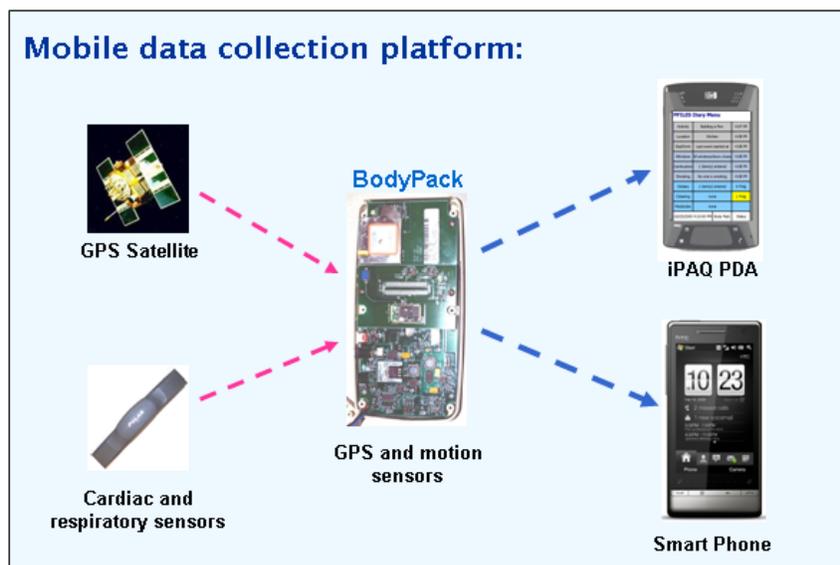
Exhibit 1. Personal Health Monitor system for ambulatory PTSD and TBI assessment

The PHM is typically carried in a pocket or purse, or using a cell-phone belt clip. The BodyPack can be carried in a hip-pack or purse, or belt-mounted. The small physical size and portability enables data collection in almost any environment and social setting, and at any time of the day. .

2.2.2.   Data Entry Forms and Diaries

The Personal Health Monitor contains a collection of available self-report health assessment instruments, such as the PTSD Checklist – Military or the Pittsburgh Sleep Quality Index (PSQI). It also contains a collection of objective sensor instruments, such as a 3 -axis accelerometer for body motion and a Polar chest belt for cardiac pulse. To configure a set of instruments for a particular clinical or research use, a subset of the available instruments can be selected and organized in the PHM database as a system.   Each system has a name, a description, and an identifi cation number.   For example, System #2 may contain four psychometric instruments (i.e., PTSD-CL, PSQI, mini-POMS, and HADS), while System #3 may contain three psychometric instruments (i.e., PTSD-CL, PSQI, mini-POMS) plus three behavioral instruments (e.g., diet, activity, and substance use).

In addition to the system definition is the use case protocol.   A protocol file (e.g., protocol.ini) declares which system is to be used for a specific clinical or research use and contains variables which affect ho w the system works. For example, protocol-A.ini and protocol-B.ini may both use the same system (e.g., System #2), but may differ in the frequency of data collection for one or more of the psychometric instruments. Therefore, by configuring various systems and tailoring systems using protocol files, the PHM is easily adapted to meet specific needs of a research study or clinical application by simply selecting the measures comprising a system and altering system attribute variables in a protocol file,

The PHM implements a set of interactive forms for self -reported entry of health status, diet, activity, behavior (e.g., substance use), environmental, and other information. Consider Test System#6 as shown in Exhibit 2A. Tapping a button on the Home Menu records a time-stamped event and invokes one or more forms, submenus or questionnaires. In this system configuration, tapping on **Baseline** (2A) displays a submenu of baseline instruments (Exhibit 2B), which tapping on **BrainGames** displays a submenu of cognitive assessments (Exhibit 2C). Each form, submenu, and questionnaire is based on a programmable database scheme, enabling reconfiguration according to the specific needs of the investigator or clinician.

Panel A.   Panel B.   Panel C.
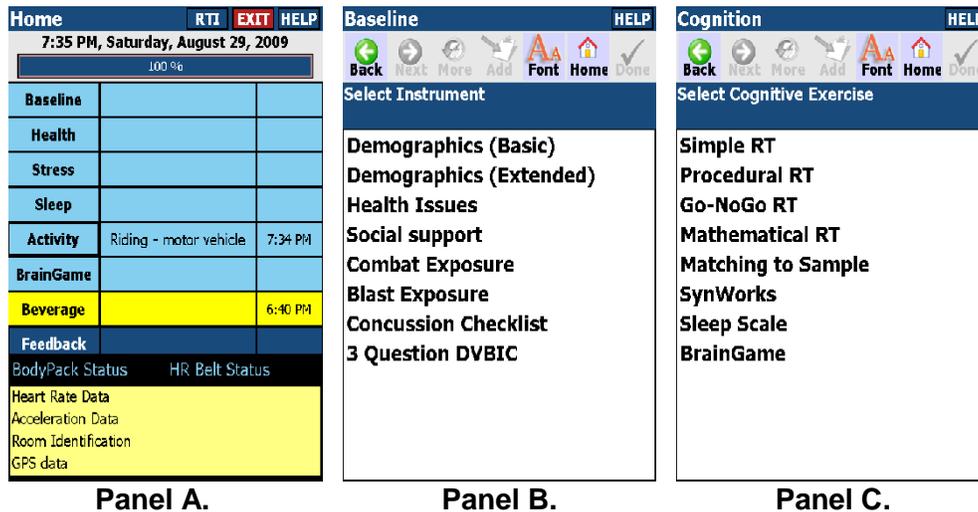
Exhibit 2. Touch-enabled top form and secondary instrument menus.

The PHM forms processor uses an object-oriented data structure to define the elements of each data entry form. The data structure includes a title, a button bar, an information/ question panel, and an input selection object. Various data selection objects are supported, including a simple selection list (Exhibit 3A), a multiple check-off list (Exhibit 3B), and a logical check-off list (Exhibit 3C). In Exhibit 3C, "Prescribed", "Over the counter), or both can be checked, however if "No medicines" is check ed, the other two are automatically cleared. All of the text is contained in a language -linked data table, supporting multiple languages by a simple language selection form, or in a system protocol file.

| Panel A. | Panel B. | Panel C. |
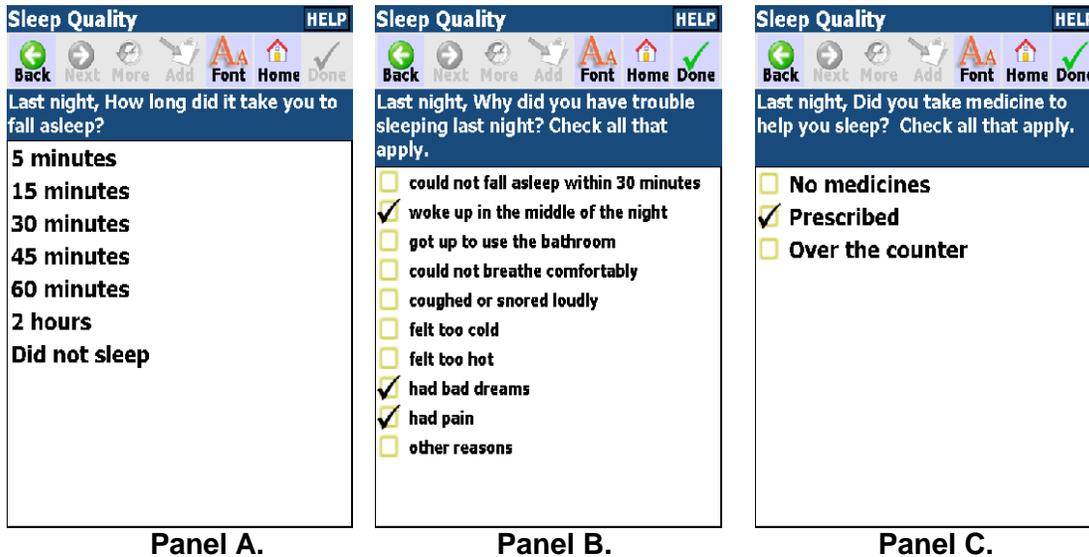
Exhibit 3. Single and multi-selection menus are used for questionnaire data.

To track patient, or participant, behaviors and environmental encounters, a hierarchical ac tivity menu system was developed. For example, the activity diary begins with a common activity menu, labeled "Frequent Activities" (Exhibit 4A). This initial list provides for quick selection based on the most common activities and activity groups accor ding to our prior EPA field evaluations.

In the following example (Exhibit 4A, 4B, 4C), a user was about to perform an activity that was not on the Frequent Activities list. By tapping **MORE Activities**, a comprehensive, categorized activity menu is displayed. The user then followed the hierarchical activity menu series to report the beginning of an "exercise" behavior.

To track dietary intake and beverage consumption, including alcoholic beverages, a hierarchical dietary menu system is employed. In th e next example (Exhibit 5), the user is reporting consumption of an alcoholic beverage. Diet menus terminate with a quantity menu to self -estimate consumption.

Nearly all of the baseline, psychological, and behavioral instruments have been entered in th e database. These will be completed and tested during the first quarter of year 2. The cognitive assessments have not been started as our subcontract with Activity Research Services has been delayed. We expect this to be resolved in the first quarter of year 2, and that the cognitive instruments will be completed by the second quarter of year 2.

Panel A.   Panel B.   Panel C.
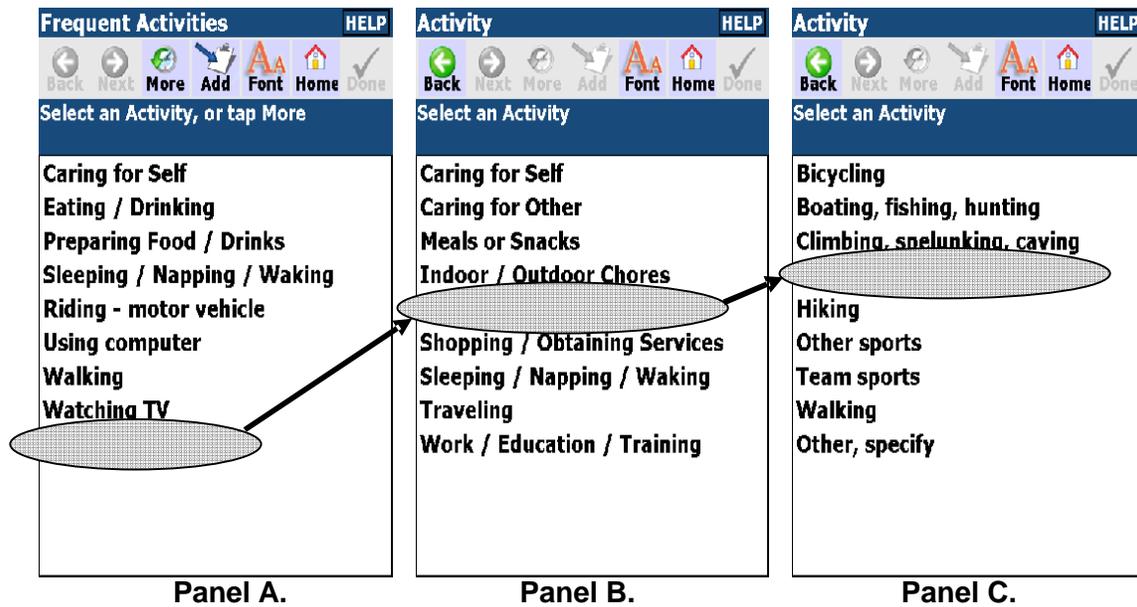
Exhibit 4. Daily activities are captured in the moment using multilevel menus.


Panel A.   Panel B.   Panel C.
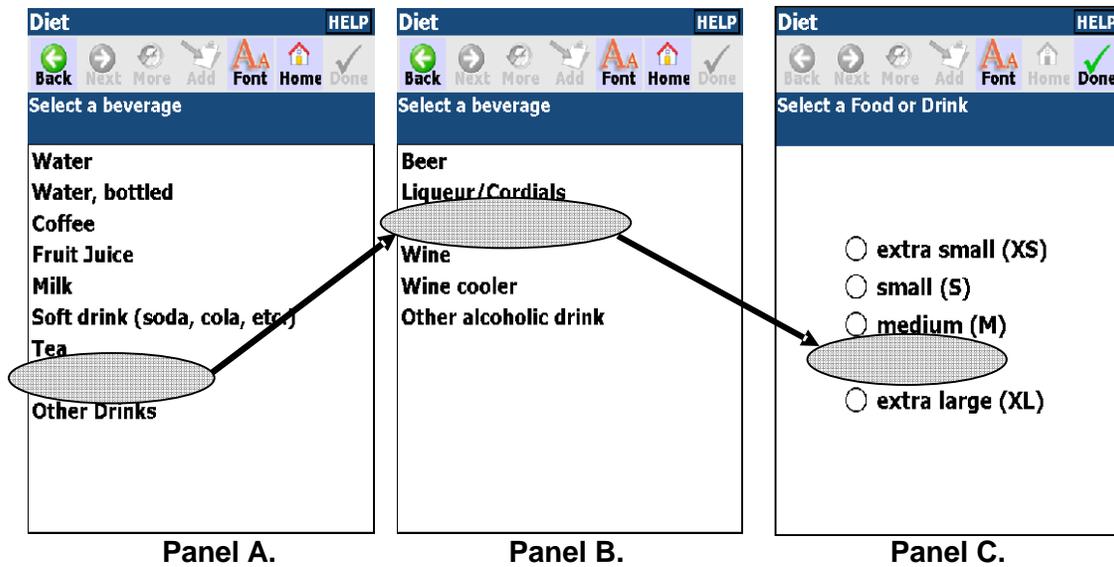
Exhibit 5. Substance use is captured in the moment using multilevel menus.

2.3. Task 3: Conduct tests and modifications to maximize usability and minimize burden

The purpose of this task is to test the functionalit y and usability of prototype data collection entry forms of the Personal Health Monitor under controlled conditions by knowledgeable development personnel.

Project personnel will exercise all instrument functions and rate usability, as well as document an y non-functionality and suggestions for improvement. During this period we will identify usability problems in menus, forms, screens, and formatting, make appropriate software revisions, and retest until specific acceptance criteria are met.

The test users will carry the devices and use them throughout one or two days to get an appreciation of usability and burden, including user interactions, physical attributes (weight and size), and social attributes of carrying such as device. We will also evaluate of battery life, charging and recharging requirements, data storage issues, and data offloading constraints. To evaluate all of the developed functions and potential data entry forms, users will enter data according to test scripts that include all data entry forms, individual form elements, form menus, navigation buttons, and other user interactions.

While unit testing of software components have been ongoing as part of the development process, all of the psychometric instrument have not been coded, and therefore the data entry forms are not complete. Therefore Task 3 is not finished. This work will be completed during the first quarter of year 2.

2.4. Task 4: Evaluate and validate our tools and methodologies in scripted field tests

The purpose of this task is to validate the functionality and further evaluate the usability of the integrated Personal Health Monitor prototype under controlled, field conditions. To evaluate all of the developed functions and potential data entry forms, users will again enter data according to test scripts that mimic expected activities, health issues, and behaviors expected of healthy users, PTSD patients, and TBI patients. A set of scripted activities (e.g., meals, walking, commerce, social interactions, and other typic al activities) will be developed and exercised by the test users each test day. The scripting will include hypothetical onset of psychological and somatic symptoms at specific times of day, so that such test data are taken, time-stamped, and stored for validation of the data collection methods.

Some test users may also be asked to use the system under non -scripted conditions, following the scripted tests. This would permit some level of assessment of user functionality, usability, and burden under uncontrolled, more natural, conditions. Some users may be asked to play a video game or perform some minor psychologically arousing or stress producing task, such as repeatedly subtracting a number (e.g., 13) from an initial number (i.e., 734). This would enab le evaluation of the device to detect a change in psychophysiological measures under a relatively benign, yet psychologically arousing situation.

The test users will carry the devices and use them throughout the day and night for at least 7 days to get an appreciation of usability and burden, including user interactions, physical attributes (weight and size), and social attributes of carrying such as device. This will also permit it the evaluation of battery life, charging and recharging requirements, data storage, and data offloading constraints.

Since a complete prototype is needed to do these evaluations, no work has been conducted on Task 4 , This work will be performed during the second and third quarter of year 2.

3. KEY RESEARCH ACCOMPLISHMENTS

? A prototype Personal Health Monitor (PHM) for Ambulatory PTSD (and TBI) Assessment has been developed which integrates the collection of subjective health information, daily activities and behaviors, and objective physiological and environmental measurements in a handheld data collection system.

? A variety of physical, psychological and social measures are available for investigator selection, such as the PTSD Checklist – Military, Pittsburgh Sleep Quality Index, Beck Anxiety Inventory, Concussion Checklist, , and Interpersonal Support Evaluation List.

? Psychometric health scales can be used in concert with self-reported daily stressors and behavioral diaries, such as work stress, dietary intake, substance use, and exercise patterns.

? Passive monitoring of heart rate variability enables arousal assessment, while passive motion and location sensors enable indirect assessment of mobility, vigor, and social interaction.

? Clinicians and research investigators are able to customize data collection protocols by selecting a subset of available assessment, diary, survey and sensor modalities to suit their needs using a set of protocol definition files and database structures.

4. REPORTABLE OUTCOMES

4.1. Publications and Presentations

? Kizakevich, P., Spira, J.L., Hubal, R.C., McCartney, M.L., Reeves, D., & Elsmore, T.. (2009). *Personal Health Monitoring for Ambulatory PTSD and mTBI Assessment*. Poster presented at Military Health Research Forum, Kansas City, MO, Invited.

4.2. Intellectual Property

? No patents or disclosures have been filed.

? RTI plans to copyright the PHM source code and user interface

4.3. Funding applied for on the basis of this work

? A CDMRP concept proposal has been applied for under Funding Announcement W81XWH-09-PH/TBIRP-CA. The proposal, called "PHIT for Duty, a Personal Health Improvement Tool for PH and TBI", would add to the personal, assessment features of the PHM with the addition of personalized health intervention strategies to monitor health status, build resilience, improve wellness, maintain compliance, and enhance recovery

? A DMRDP pre-proposal has been submitted for under Funding Announcement W81XWH-09-DMRDP-ARATDA. The proposal, called "Mobile Technologies for Improving Health in Casualties and At-Risk Personnel", would add to the personal, assessment features of the PHM with the addition of personalized health intervention strategies to monitor health status, build resilience, improve wellness, maintain compliance, and enhance recovery. If accepted, the DMRDP project would not only extend the technology development, but evaluate the usability of the prototype PHIT system in a cohort of normal, PTSD, and TBI patients.

5. CONCLUSIONS

? The Personal Health Monitor enables the assessment of stressors and psychophysiological reactions in real time, offering new capabilities for psychological health research and clinical assessment.

? The Personal Health Monitor enables collection of personal health data with privacy and anonymity, which may improve the quality, frequency, and accuracy of the psychometric assessments. The disassociation of self-report measures from the clinical setting may offer a more realistic portrayal of mood, feelings, and other data because of the innate privacy of the method

? Using mobile handheld computer and smart phone technology, the Personal Health Monitor enables psychological health assessments on a more continuous basis than traditional clinical encounters.

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Whitmore, Roy, Breda Munoz, Paul Kizakevich. "Comparison of Alternative Methods for Longitudinal Studies on Human Exposure-related Activities." International Society of Exposure Analysis, Paris, September, 2006.

7.   *APPENDIX A*

7.1.   **Use Case 1 – Combat Operational Stress Assessment**

<u>Objective</u>:
Assess the daily functioning of deployed service members to understand how stress develops over the course of deployment.

<u>Problem</u>:
Little is known about the precursors for developing combat-related PTSD. Combat exposure and re-deployment, while important predictors, do not help us understand why most of those with these risk factors do not go on to develop PTSD. Research is being conducted on genetic and other predisposing factors. Yet in the meantime, another route to appreciating the who develops deployment-related PTSD and when they develop it may lie in detecting onset of symptoms or lifestyle concomitants. For instance, more regular assessment of sub-threshold sleep, mood, psychophysiological, and cognitive functioning may allow us a better indicator of who is PTSD-prone so that early intervention could curtail full onset. Such an analysis could be conducted in a) any deployed military member, while in-country during some critical period (e.g. six or nine months into deployment cycle), b) those with highest risk factors (combat exposed, multiply deployed) while in-country, or c) service members who have recently returned from deployment; d) this approach could also be used to appreciate the stressors facing the typical service member over the lifetime of a deployment by following them for a week prior to deployment, during a week early in and then again later in their deployment, and when they return from deployment for a week in the first month, and then again several months later.

<u>Hypotheses</u>:
Used for an initial understanding of the incidence, prevalence, and time-course of multiple stressors in a combat arena, descriptive data can be captured for a wide range of service members. Within this descriptive data, however, several deductive hypotheses can be considered. Dependent Measures include STRESSORS (combat exposure, number of deployments, temperature, number of missions, etc) and STRESS RESPONSES (psychological, psychophysical, lifestyle). It is reasonable to suspect that:

- Stressors and stress responses will continually increase over the course of a deployment
- Those with highest risk factors (combat exposed, multiply deployed) while in-country will have greater stress responses than others, independent of external stressors
- Stress responses during deployment will predict who experiences greater stress response post-deployment, independent of stressors

<u>Research gap addressed</u>:

This use case addresses the research gap of measures in screening, detection, and diagnosis, in that it is focused on the development, improvement, and/or validation of resources to guide operational and clinical decision making, and also includes studies on the mechanisms of resilience and evaluation of existing interventions.

Research areas addressed:
This use case addresses prevention, and examines factors independent of exposure or other baseline predictors (age, rank, sex). This use case gets at treatment predictors, in determining progress with this type of therapy, specifically if there is lack of response in targeted symptoms, then it may be necessary to move the patient to another treatment modality that better fits with the manifested symptoms.

Methods:
The Personal Health Monitor (PHM) will be worn by service members daily for a one week period for one week prior to deployment, for one week every three months during deployment (as feasible), as well as every three months following deployment to predict who will develop post-deployment problems. Measures are meant to be as unobtrusive as possible, with alarms indicating response to questions that should only take a couple of minutes, a few times per day. Exceptions are once per week assessments that may take up to 20 minutes (e.g. stress reactivity, neuropsychological assessment).

Dependent Measures:
- Assessment of Stressors:
    § Combat Exposure (baseline, 1x/week during deployment, 1x post deployment)
    § Multiple Deployments (baseline, 1x post-deployment)
    § Multiple Missions within a deployment (baseline, 1x/week during deployment, 1x post deployment)
    § Temperature (and time spent outside) (daily when used)

- Assessment of Stress Responses
    § Psychological
        • Neuropsychological (Simple RT; Forced Choice; Memory) (1x/week of use)
        • Mood (mini-POMS) (daily when used, split over time)
        • Trauma (PCL-m; IES; emotional stroop) (1x/week when used)
    § Psychophyiscal
        • HR/HRV (ambulatory HR/HRV; 1x/week for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)

    § Lifestyle
        • Sleep (1st day of use average, then daily if positive)
        • Pain (1st day of use average, then daily if positive)
        • Risk Behaviors (1st day of use average, then daily if positive)
        • Diet (including recreational Substance Use – 1 meal/day, plus ETOH use)

- Exercise (daily activity recall))
- Socializing (daily activity recall)
- Recreation (daily activity recall)

Analysis and results:
- Repeated measures MANCOVA can be used to compare changes in related dependent measures over time and for various groups (e.g. forward vs rear deployed). Regression Models can be employed to determine factors leading to adjustment difficulties:
§ Multiple for models of risk factors leading to trauma symptoms;
§ Logistic for models of risk factors leading to PTSD criterion).
Complex Modeling (including SEM) can be used to test theories of specific factors that lead to resilience or trauma outcomes.

Conclusions and implications:
The use of a personal monitoring device to track the daily experiences and reactions of warfighters throughout the deployment cycle is a novel, and potentially invaluable tool for a) more clearly understanding the time-course of stressors and responses for different segments of the military at different stages of deployment, and b) determine risk factors for sensitizing service members and protective resiliency factors that may lead to post traumatic stress disorder and other psychological sequellae of combat.

7.2. Use Case 2 – Suicide Risk

Objective:
Assess the potential for suicidal behavior (ideation, intent, attempt, completion) in order to implement improved methods of prevention, risk assessment, and emergency interventions.

Problem:
Although military suicides have traditionally been at or below the national civilian norms, since the conflict in the Middle East, suicides have risen dramatically in the military. Several risk factors have been identified with suicidal behavior (ideation, intent, attempts, and completions), including demographics, combat deployment, combat exposure, depression, relationship distress, PTSD, and alcohol abuse. In the past, these factors have been determined from civilian research, as well as through post-mortem or post-morbid psychological autopsies. Current efforts by the military include collecting baseline data on cohorts of military members and following them over time to determine risk factors that predict suicidal behavior. Such efforts to determine baseline predictors of future events is laudable. However, in those with known risk factors, it could be of great value to continually assess ongoing fluctuations in levels of suspected risk factors.

Hypotheses:
This monitoring device can be used as secondary prevention in those who are determined to be at greatest risk for suicidal behavior, due to known risk factors in order to:

- Achieve a better understanding of the risk factors that lead to suicidal behavior. This could include confirmation of the suspected pre-existing risk factors such as deployment, combat exposure, and failed relationships, as well as current risk factors such as alcohol abuse, relationship distress, depression, and PTSD. However, additional risk factors that include sleep, pain, socializing, anger, risk taking, and other daily lifestyle factors could be predictive of suicidal behaviors not easily detected from remote or periodic assessments.
- Better appreciate whether it is the risk factors themselves or fluctuations of such risk factors that best account for suicidal behavior. It is predicted that major fluctuations in risk factors (mentioned above) will add predictive value to suspected baseline predictors.
- Understand the relationship between pre-existing exposures, behavioral risk factors, psychological risk factors, and psychophysiological status – and their relationship to suicidal behavior.
- Provide a mechanism for more closely monitoring risk factors and suicidal behaviors such as ideation and intent. When combined with a smart-phone that has internet capability, a report can be generated and sent to a case manager assigned to monitor those in a high-risk program.
- Determine whether a handheld monitoring device could be useful for early intervention and prevention of more serious suicidal behaviors. If a report is sent to a case manager that indicates surges in risk factors, the case manager can intervene to curtail suicidal behaviors.
- Determine which type of intervention is most effective in curtailing suicidal behavior.

Research gap addressed:
This use case can be employed in primary prevention, secondary prevention of those at greatest risk, and post-deployment re-integration strategies.

Research areas addressed:
In order to better understand prevention and treatment of suicidal behaviors, research can be conducted to better understand baseline and ongoing risk factors, the role of momentary surges in risk factors, the benefits of close monitoring for interventions, and determining best practices for interventions in high risk populations. Appreciating the relationships between environmental, psychological, and psychophysical reactivity will also be possible with this approach.

Methods:
For assessment methodologies: The Personal Health Monitor (PHM) will be worn by service members determined to be 'at risk' due to a weighted formula determined from a combination of combat deployment, combat exposure, relationship distress, depression, alcohol abuse, and suicidal ideation. Users could be issued the device for a period of three months, if used for assessment only

For intervention methodologies: In addition to assessment, the PHM will relay information on a daily basis to a case manager who will regularly monitor for elevated risk, and determine the best course of intervention (such as telephone contacts, triaging

into groups, or individual counseling, or even admission to an in-patient psychiatric ward if need be). Users c ould be issued the device for as long as they are determined to be 'at risk' and in the case management program.

In a randomized clinical trial, the control group could be assigned the device for assessment only, and involved in treatment as usual care (s uch as weekly support groups, or case management that does not utilize the PHM).

Measures are meant to be as unobtrusive as possible, with alarms indicating response to questions that should only take a couple of minutes, a few times per day. Exceptions are once per week assessments that may take up to 20 minutes (e.g. stress reactivity, neuropsychological assessment).

Dependent Measures:
- Baseline Risk Factors (one time at baseline):
    - § Demographics
    - § Combat Exposure
    - § Deployment information
    - § Relationship dissolution within the prior year
    - § Demographics
- Lifestyle and Behaviors
    - § Alcohol Use (once per week average, then daily if positive)
    - § Risk Behaviors (once per week average, then daily if positive)
    - § Relationship Discord (once per week average, then daily if positive)
    - § Sleep Functioning (once per week average, then daily if positive)
    - § Pain (once per week average, then daily if positive)
    - § Diet (one meal per day)
    - § Exercise (daily activity recall)
    - § Socialization (daily activity recall)
    - § Recreation (daily activity recall)
- Psychological Status
    - § Trauma (PCL, IES) (1x/week)
    - § Mood (mini-POMS) (daily for subscales flagged as significant; weekly for other scales)
    - § Neuropsychological (Simple RT; Forced Choice; Memory) (1x/week of use)
    - §
- Psychophysiological Reactivity
    - § HR/HRV (ambulatory HR/HRV; 1x/week for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)

Analysis and results:
- For assessment only, modeling can be used to determine the relationship between risk baseline risk factors, ongoing factors, and suicidal behaviors.
- For an RCT, a group by time ANOVA can compare a case manager closely integrated with the PHM compared to a case manager that is not integrated with or utilizing the PHM.

Conclusions and Implications:

      The use of a personal monitoring device to track the daily experiences and reactions of those deemed to be at risk has the potential to offer important new information about which factors are most predictive of suicidal behavior. In addition, integrating a case manager fully into such a system has the potential to reduce negative outcomes and improve recovery for such persons.

7.3. Use Case 3 – Therapeutic Intervention

Objective:

Monitor service members to assess progress over the course of treatment, and support disposition recommendations such as readiness to return to duty, remain in limited duty capacity, or recommend separation.

Problem:

Determination of progress for one's recovery from psychological illness is typically based upon periodic clinician interview or even rarer single assessment measure. In research, such progress is typically measured by a more thorough assessment battery every at study entry, at completion of the intervention, and possibly at a follow -up point or two. However, these intermittent assessments may lack full validity because 1) the patient may respond with an attitudinal set (either more or less well), and 2) these specific dates may not be representative of the patient's average functioning. More periodic ambulatory assessments has the potential to offer more accurate measurements of patient progress. It can also give a better indication of the patient's daily range of fluctuations in various areas of functioning – periodic assessment may only pick up the average, rather than the degree of fluctuations experienced by the patient. Finally, it can offer the clinical research or provider greater insight into the course of the intervention, or how each patient is responding to this particular intervention. Analogies include taking blood pressure and heart rate once at the cardiologist's office, versus ambulatory monitoring to better diagnose patients with cardiac problems; undergoing an EEG at the neurologist's office versus ambulatory monitoring to detect seizure disorder, and taking a fasting glucose every few months at the doctor's office versus a Hemoglobin A1c that averages blood sugars over the past three months for better determination of diabetes. Similarly, regular ambulatory monitoring of psychological factors can offer a far greater accuracy and understanding of progress over time than traditional periodic measures.

Hypothesis/es:

Different deductive hypotheses will be developed for different clinical interventions. However, several inductive analyses could be assessed from ambulatory assessments during the course of therapy:

- Understand the fluctuations in psychological functioning during the course of therapy (In exposure therapy, expect some worsening for a time before improvement; in arousal control methods, expect some immediate temporary bene fit that may not be sustained, etc).
- Understand the degree of fluctuations in psychological functioning during the course of therapy. Degree of stability in psychological functioning will assist in

determining readiness return to duty, or need to remain in therapy for be medically separated.

- Understand the impact of the particular type of therapy on patients in general, or on particular patient types. (For instance, it could be that more reflective patients respond to different elements sooner or later or more fully than more concrete patients to a particular therapeutic modality.)
- End of therapy decisions will be more accurately determined than when a protocol has been completed, or when termination decisions are based upon an end of protocol single assessment is used. This will be reflected in accuracy of disposition (such as readiness to return to duty).
- Through tracking compliance with homework assignments, compliance can be more accurately used to predict outcome (e.g. in-vivo practice independently influencing PCL scores).
- Can therapists enhance therapeutic effectiveness by getting reports of daily and weekly objective and subjective ambulatory assessments, and therefore being able to adjust therapeutic interventions accordingly?

Research gap addressed:
This use case addresses the research gap of treatment and intervention, in that it relates to both the deployed and non-deployed military settings with focus on novel treatment approaches or adaptations of existing treatments across a continuum of acute through chronic care. Its ultimate goals include improving therapeutic intervention, termination, and disposition recommendations, affecting the well-being of patients.

Research areas addressed:
This use case addresses treatment predictors, in determining who will improve in psychotherapy.
It addresses objective measures (psychophysiology; neuropsychological functioning) and lifestyle areas not often assessed by providers including lifestyle assessment, assessing social activity, diet, exercise, sleep, relationship issues, as well as more detailed appreciation of pain, substance use, etc. Further, this approach targets psychotherapeutic methods, such as tracking homework assignments (such as in-vivo exposure frequency, duration, and SUDS levels, etc.).

Methods:
Patients undergoing psychotherapy would be asked to wear the Personal Health Monitor (PHM) during the course of their therapy. Alarms would go off periodically throughout the day to inquire about various aspects of functioning, as well as therapeutic assignments (such as homework, further serving as a reminder – alarms can be set with the therapist to remind the patient at the most appropriate times of the day). This is meant to be as unobtrusive as possible, with each query taking only a few seconds or minutes, except for a 20-minute assessment once per week for objective neuropsychological and psychophysiological assessment.

Dependent Measures:
- Baseline Risk Factors (one time at baseline):

- § Demographics
- § Combat Exposure (if relevant)
- § Deployment information (if relevant)
- § Relationship dissolution within the prior year
- § Demographics
- Lifestyle and Behaviors
    - § Alcohol Use (once per week average, then daily if positive)
    - § Risk Behaviors (once per week, then daily if positive)
    - § Relationship Discord (once per week, then daily if positive)
    - § Sleep Functioning (once per week average, then daily if positive)
    - § Pain (once per week average, then daily if positive)
    - § Diet (one meal per day)
    - § Exercise (daily activity recall)
    - § Socialization (daily activity recall)
    - § Recreation (daily activity recall)
- Psychological Status
    - § Trauma (PCL, IES) (1x/week)
    - § Mood (mini-POMS) (daily for subscales flagged as significant; weekly for other scales)
    - § Neuropsychological (Simple RT; Forced Choice; Memory) (1x/week of use)
- Psychophysiological Reactivity
    - § HR/HRV (ambulatory HR/HRV; 1x/week for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)

Analysis and results:

Therapeutic progress and readiness to return to duty can be obtained by analysis of objective measures such as neuropsychological and psychophysiological assessment, as well as subjective measures that also offer a measure of consistency in psychological functioning. These can be viewed qualitatively for individual patients, or in aggregate format using statistical analysis for groups in order to determine the efficacy of novel therapies, or comparison of therapies.

Neuropsychological functioning can compare the user to themselves, as well as to established norms. Repeated measures condition x time ANOVA can determine degree of psychophysiological reactivity for a group of patients or between groups of patients using different interventions. Autocorrelation can offer an indication of fluctuation in symptoms for each subjective measure of psychological functioning for individuals or groups of patients.

Conclusions and implications:

Evidence-based interventions are being utilized more fully in response to patients returning from war, and this has translated into working with non-combat patients and civilians. However, new challenges include better understanding 1) the impact of specific therapies on patients' entire life, not merely targeted symptoms, including both subjective and objective measures, 2) more accurate measurements for therapeutic efficacy, 3) more accurately adjusting therapies to boost therapeutic response through

more accurate and timely assessment, and 4) obtaining better indications of readiness to terminate and return to duty or be separated.

7.4. Use Case 4 – Health Behaviors

Objective:
Assess post-deployment health behaviors of combat veterans to better understand the association between combat deployment and reintegration. Health behaviors can also be examined as a predictor for recovery from combat stress symptoms, development of PTSD and mTBI recovery.

Problem:
Although Post deployment health assessments (PDHA) and reassessments (PDHRA) are routinely given to returning veterans of OIF/OEF, there is insufficient appreciation of how lifestyle behavior is affected by combat, and how such lifestyle behaviors influence successful re-integration.

Hypothesis/es:
- Combat deployment significantly impacts post-deployment lifestyle.
- Post-deployment lifestyle impacts readjustment as indicated by mood, relationships, cognitive functioning, quality of life, and psychophysiological reactivity.
- Lifestyle functioning is affected by combat deployment independently of combat-related stress (PCL) and in turn affects readjustment independent of combat stress (PCL).
- Health behaviors are predictive of recovery from combat stress symptoms, development of PTSD and recovery from mTBI.

Research gap addressed:
This use case addresses the research gap of epidemiological studies, in that it is focused on predictors of post-deployment reintegration factors, the evaluation of both new and existing measures, and the association of PTSD and mTBI with reintegration and quality of life.

Research areas addressed:
This use case assesses the influence of health behaviors on the time-course of mTBI and combat related stress and stress disorders.

Methods:
The Personal Health Monitor (PHM) will be worn by post-deployment service members once per week each month for six months to determine the relationship of health behaviors to combat deployment and subsequent reintegration.
Single group design could be used with post-deployment personnel only. Ideally, pre-deployment health behaviors could be established by having research participants where the PHM for one week prior to deployment (prior to the initiative of 'work-ups' to get a more standard indication of pre-deployment behavior).

A different type of design could utilize a small comparison group of similar SES/MOS military participants who are eligible for deployment, but who do not deploy on the same cycle.

Measures are meant to be as unobtrusive as possible, with alarms indicating response to questions that should only take a couple of minutes, a few times per day. Exceptions are once per week assessments that may take up to 20 minutes (e.g. stress reactivity, neuropsychological assessment).

<u>Dependent Measures</u>:
- Baseline Risk Factors (one time at baseline):
    - § Demographics
    - § Combat Exposure
    - § Deployment information
    - § Relationship dissolution within the prior year
    - § Demographics/MOS
- Lifestyle and Behaviors
    - § Alcohol Use (daily)
    - § Risk Behaviors (daily)
    - § Relationship Functioning (1 time per assessment week)
    - § Sleep Functioning (daily)
    - § Pain (once per week average, then daily if positive)
    - § Diet (one meal per day, alternating each day)
    - § Exercise (daily activity recall)
    - § Socialization (daily activity recall)
    - § Recreation (daily activity recall)
- Psychological Status
    - § Trauma (PCL, IES) (beginning and end of weekly assessment)
    - § Mood (mini-POMS) (daily for subscales flagged as significant; beginning and end of weekly assessment for other scales)
    - § Neuropsychological (Simple RT; Forced Choice; Memory) (1x/week of use)
- Psychophysiological Reactivity
    - § HR/HRV (ambulatory HR/HRV; beginning and end of weekly assessment for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)
- TBI Assessment
    - § Blast and head trauma exposure (one time)
    - § Post-concussive Syndrome assessment (PDHRA questions; SAC; automated MACE); 1x/assessment
- Quality of Life
    - § SF-12 (one time per assessment week)

<u>Analysis and results</u>:
- ANOVA will determine if health behaviors are worse following combat deployment than prior to deployment and/or to a comparison non-deployed matched group.

- Regression models will determine if and which poor health behaviors are predictive of reintegration, including outcomes such as mood, combat stress, relationships, quality of life, and recovery from TBI (where relevant).
- Health behaviors will be examined as independent factors, beyond those associated with combat stress or head injury.

Conclusions and implications:
The role of health behaviors has been widely recognized in most areas of medical and public health. However, it's role has been understudied with regard to psychological factors. This is especially relevant in deployment health, since deployment is suspected to negatively impact health behaviors in this young and otherwise healthy population. If health behaviors are found to play a role in reintegration, then these activities can be more intensively targeted as a military preventive medicine initiative, both formally within the command structure, and through public health educational initiatives.

7.5. Use Case 5 – Screening for and Tracking mTBI

Objective:
The Personal Health Monitor (PHM) can be used to assist in mTBI screening, time-course, and commencement of rehabilitation for more rapid recovery.

Problem:
Mild Traumatic Brain Injury (mTBI) affects hundreds of thousands of service members returning from the conflict in the Middle East, as well as over one million civilians due to sports or motor vehicle accidents each year. However, there is insufficient screening for determining incidence and recovery from mTBI. Further, although NIMH and the largest NeuroRehabilitation Associations in the United States all agree that cognitive rehabilitation is necessary for improving recovery from lingering TBI, there is inadequate treatment for those who have sustained mTBI in combat. This is due to several reasons, including the suspicion that most mild forms of TBI recovery within the first three months of the injury. However, determining who exactly those persons will be is not well addressed, since a "watch and wait" attitude often lets those who have lingering post-concussive symptoms receive inadequate re-assessment or simply fall through the cracks. By the time lingering effects are recognized, the service member either has separated from military duty, or it is too late for effective rehabilitation to commence. Utilizing a Personal Health Monitor (PHM) for those with suspected mTBI will help alleviate this problem and allow the afflicted service member to receive appropriate and timely rehabilitation.

Hypothesis/es:
- Combat deployment significantly impacts post-deployment lifestyle.
- Post-deployment lifestyle impacts readjustment as indicated by mood, relationships, cognitive functioning, quality of life, and psychophysiological reactivity.
- Lifestyle functioning is affected by combat deployment independently of combat-related stress (PCL) and in turn affects readjustment independent of combat stress (PCL).

- Health behaviors are predictive of recovery from combat stress symptoms, development of PTSD and recovery from mTBI.

Research gap addressed:
This use case addresses mTBI, where rather than watching and waiting for a period of limited duty to determine if symptoms are resolving (often up to six months), more regular assessment of functioning can determine if progress is not being made so that cognitive rehabilitation can begin earlier (when improvement has a chance to optimally assist brain function recovery and limit psychosocial dysfunction).

Research areas addressed:
This use case addressed the assessment and rehabilitation of service members who have sustained a brain injury.

Methods:
    The Personal Health Monitor (PHM) will be worn by post-deployment service members who have sustained a head trauma continually until it has been determined that there is no longer continued post-concussive syndrome or associated risk. A randomized control design can assign half the subjects to a treatment as usual (TAU – typically watch and wait) or a PHM group that is assessed on a more regular basis for up to three months. Patients sustaining PCS symptoms after that time should be referred to treatment. The PHM can also be used during rehabilitation treatment to determine progress and offer feedback to therapists for individualized attention and refinement of interventional methods.
    Measures are meant to be as unobtrusive as possible, with alarms indicating response to questions that should only take a couple of minutes, a few times per day. Exceptions are once per week assessments that may take up to 20 minutes (e.g. stress reactivity, neuropsychological assessment).

Dependent Measures:
- Baseline Risk Factors (one time at baseline):
  - § Demographics
  - § Combat Exposure
  - § Deployment information
  - § Relationship dissolution within the prior year
  - § Demographics/MOS
  - § Head Trauma exposure and Post-concussive Syndrome ratings
- Lifestyle and Behaviors
  - § Alcohol Use (daily)
  - § Risk Behaviors (daily)
  - § Relationship Functioning (1 time per assessment week)
  - § Sleep Functioning (daily)
  - § Pain (once per week average, then daily if positive)
  - § Diet (one meal per day, alternating each day)
  - § Exercise (daily activity recall)
  - § Socialization (daily activity recall)

- § Recreation (daily activity recall)
- Psychological Status
  - § Trauma (PCL, IES) (beginning and end of weekly assessment)
  - § Mood (mini-POMS) (daily for subscales flagged as significant; beginning and end of weekly assessment for other scales)
- Psychophysiological Reactivity
  - § HR/HRV (ambulatory HR/HRV; beginning and end of weekly assessment for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)
- TBI Assessment
  - § Blast and head trauma exposure (one time)
  - § Post-concussive Syndrome assessment (PDHRA questions; SAC; automated MACE); 1x/assessment
  - § Neuropsychological (Full ANAM Combat Stress Assessment battery; 1x/week)
- Quality of Life
  - § SF-12 (one time per assessment week)

Analysis and results:

- Comparison of pre-deployment ANAM to current ANAM will offer an indication of severity of head trauma on functional status.
- Tracking of PCS and ANAM measures over time will offer an indication of current level of functioning and patient progress over time.
- The rate of referral to appropriate rehabilitation services will improve in those receiving the PHM versus tracking as usual.
- Therapeutic recovery will progress more rapidly if therapist are given feedback reports on areas of patient concern and progress.

Conclusions and implications:

The "watch and wait" approach to determining if mTBI will adequately recover is crude and most often ineffective in getting patients into appropriate rehabilitation services. In addition, since patients can 'rally their cognitive resources' for a brief assessment, the true impact of mTBI on cognitive functioning can often not be determined through traditional tracking. The use of the PHM specifically configured to assess person with a mTBI who have lingering PCS will help to more accurately assess PCS and associated functioning, facilitate decisions to refer to appropriate rehabilitation, and support the therapeutic efforts.

7.6. Use Case 6 – Family Stress

Objective:
Understand the stress experienced by family members and the relationship to service member stress.

Problem:
Service members returning from OIF/OEF combat deployment have enjoyed an unparalleled focus on psychological impact and adjustment. However, appreciation of the

distress experienced by family members and their influence on their readjustment has been sorely lagging behind. Recently, programs to support the reintegration process involving both service members and their families have begun, including web -based information and reintegration retreats. However, the efficacy of such approaches have not been adequately evaluated,   Both in order to better support the family members as well as their service members, a better appreciation of the daily stressors and reactions facing family members is required. Further, the effect of intervention programs (post - deployment debriefings, reintegration retreats, family therapy, etc) can be determined through the use of a Personal Health Monitor (PHM).

Hypotheses:
- The impact of combat deployment on functioning of family members prior to, during and following deployment will be determined, and predicted to be lower than prior to deployment.
- The relationship between family functioning and service member functioning will be determined, and predicted to be highly correlated.
- The impact of interventional methods on family and service member functioning will be determined.

Research gap addressed:
This use case addresses the research gap of families/caregivers, in that it is focused on measuring the impact of deployment and psychological and physical wounds on family/caregiver function as well as projects that assess the efficacy of training and support programs.

Research area addressed:
This use case addresses the relationship of family to service member well -being, as well as the efficacy of interventional program to improve re-integration.

Methods:
(Optimally, recruit families of service members assessed throughout the deployment cycle in Use Case 1, above).

- Pre deployment:
    - Assess service members and family members for 1 week
- During deployment:
    - Assess family members one week every three months
- Post-deployment:
    - Assess family members and service members one week every month for six months
- Compare participants who partake in an intervention compared to those who do not partake in that intervention.

Dependent Measures:
- Assessment of Stressors (of service member):

- § Combat Exposure (baseline, 1x/week during deployment, 1x post deployment)
- § Multiple Deployments (baseline, 1x post-deployment)
- § Multiple Missions within a deployment (baseline, 1x/week during deployment, 1x post deployment)

- Assessment of Stress Responses
  - § Psychological
    - Neuropsychological (Simple RT; Forced Choice; Memory) (1x/week of use)
    - Mood (mini-POMS) (daily when used, split over time)
    - Trauma (PCL-m; IES; emotional stroop) (1x/week when used)
  - § Psychophyiscal
    - HR/HRV (ambulatory HR/HRV; 1x/week for stress challenge conditions of rest, stress recall, cognitive stressor, and recovery)
  - § Lifestyle
    - Sleep (1st day of use average, then daily if positive)
    - Pain (1st day of use average, then daily if positive)
    - Risk Behaviors (1st day of use average, then daily if positive)
    - Diet (including recreational Substance Use – 1 meal/day, plus ETOH use)
    - Exercise (daily activity recall))
    - Socializing (daily activity recall)
    - Recreation (daily activity recall)

Analysis and results:
- Descriptive analysis can help policy makers appreciate the impact deployment on family health, and the relationship between family and service member quality of life.
- Regression Models can be employed to determine factors leading to adjustment difficulties, including the impact of deployment factors on family member distress, the impact of family member distress on service member functioning, the effects of having a psychological or physical wound on family member functioning, etc.
- Effects of Intervention: Repeated measures MANCOVA can be used to compare changes in related dependent measures over time and for family treatment groups.

Conclusions and implications:
Reintegration of service members to home life, retention issues, and even recovery from psychological and physical injury following combat deployment is reputed to be related to family functioning, yet this needs to be established through research trials. Moreover, post-deployment military family functioning has not been well researched, nor has the impact of interventions aimed at facilitating reintegration of service members and their families. Use of the PHM offers more reliable objective and subjective measures of factors related to reintegration than do single or sporadic measures.